

Application No.: 10/550,778
Amendment and Response dated February 16, 2010
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REMARKS/ARGUMENTS

The application has been amended. Entry of the amendments and reconsideration are respectfully requested.

Status of the Claims

Claims 40 and 47-70 are pending in the application prior to entry if the amendments herein. Claims 65-70 have been withdrawn from consideration by the Examiner has drawn to non-elected subject matter.

Discussion of the Amendments to the Claims

The claims have been amended to more particularly point out and distinctly claim the subject matter of the present invention. In particular, claim 40 has been amended to recite that the template is ^DPro-^LPro or ^LPro-^DPro. Moreover, the definitions of Z and Z' in claim 40 have been amended as presented herein. Additionally, claim 40 has been amended to recite the full names of the "non-standard, atypical" amino acids at their first occurrence. Claims 47-49 and 59-60 have been cancelled. Claim 65 has been amended to recite a method for treating a disorder mediated by or resulting from CXCR4 activity. Claims 66 and 67 have been amended in view of the amendment to claim 40 and to replace "acetylating" with --acylating-- Moreover, in claims 69 and 70, the reference to claim 56 has been replaced with a reference to claim 58. Various other amendments have been made as shown in the claim listing presented herewith. Support for the amendments to the claims may be found in the specification at originally filed at, for example, page 56, line 14, page 56, line 32, page 60, line 11, page 60, line 1, page 60, line 34, and at page 61, lines 1-2 and 4-6. It is respectfully submitted that no new matter has been added by way of the amendments to the claims.

Supplemental Information Disclosure Statement

The Examiner has alleged that the listing of references in the specification (page 89) is not a proper Information Disclosure Statement.

The papers by Levy and by Schwartz et al. as well as Science, 1997, 275, 1261-1264 cited on page 1 provide some scientific background on HIV.

The papers by Nakashima et al. and by Tamamura et al. cited in the paragraph bridging pages 1 and 2 provide some background information relating to an antiparallel β -sheet structure and formation of a β -hairpin by means of two disulfide bridges.

The various papers cited in the first paragraph of page 3 relate to the possible use of certain template-fixed β -hairpin mimetics in certain therapeutic areas.

The first two papers cited in the second paragraph on page 3 relate to certain sequences, other than those according to the present invention, and the third of these papers illustrates how parallel syntheses work.

The various papers cited on page 89 provide information on the tests described on pages 85-88.

Applicants respectfully submit that the foregoing papers are not deemed relevant to the patentability of the present invention as defined by the pending claims.

A Supplemental Information Disclosure Statement listing papers by Tamamura et al., Matsuzaki et al. and Otaka et al. are being submitted in a Supplemental Information Disclosure Statement which is being filed concurrently herewith. Other papers by Tamamura which are listed on page 89 of the specification and which were previously submitted in the Information

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Disclosure Statement which was filed on November 15, 2005 are not being submitted in the Supplemental Information Disclosure Statement which is being submitted herewith.

Response to the Objection to the Specification

The Examiner has objected to the abstract of the disclosure as allegedly not being descriptive of the invention claimed and for referencing the claims and specification for the definition of the claimed subject matter. Moreover, the Examiner has alleged that "the abstract asserts the compounds to be useful for treating or preventing condition [sic] that are generally considered to be unpreventable and/or difficult to treat, e.g. cancer and HIV infection." (Office Action, page 4). Additionally, the Examiner has objected to the specification as allegedly containing new matter. In particular, the Examiner has alleged that the Amendment filed on May 5, 2008, introduced new matter by substituting Lys for Arg at P1' of SEQ ID NO:1. Reconsideration is respectfully requested in view of the amendments and remarks herein.

To advance prosecution, the abstract has been amended to delete the references to HIV and cancer from the abstract. As amended, the specification recites that the compounds "have CXCR4-antagonizing properties and can be used as medicaments." Moreover, the abstract has been amended to remove all references to the description and claims.

Additionally, the specification has been amended at Table 1, to replace "Arg" with --Lys--.

In view of the foregoing, withdrawal of the objections to the specification is respectfully requested.

Response to the Claim Objections

The Examiner has objected to claim 40, stating that it is 30+ pages in length and alleging that "the arrangement of the variables in the claim would benefit from reordering." (Office

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Action, page 4). Moreover, the Examiner has indicated that “[t]he first occurrence of non-standard abbreviations in the claim should be accompanied by their full name.” (Office Action, page 5). The Examiner also has objected to claims 40 and 47-57, alleging that “the order of the amino acids should be presented in a manner that represents the peptide being described from left to right, as is standard convention.” (Office Action, page 5).

As amended, claim 40 is much shorter than previously presented and contains only a few variables. Moreover, Applicants respectfully submit that the “model” proposed by the Examiner for representing the compounds of the invention is not deemed suitable as it relates to a molecule which is still attached to the resin, not a molecule cleaved from the resin. Additionally, the amino acids are no longer defined by their “type” but, explicitly, in accordance with the actual exemplification. Furthermore, the “non-standard, atypical” amino acids are now accompanied by their full name at their first occurrence. Accordingly, it is respectfully submitted that the amendment to claim 40 overcomes the above-identified objections to claims 40 and 47-57.

The Examiner has objected to claims 59 and 60 under 37 CFR §1.75(c) as allegedly being of improper dependent form. In particular, the Examiner has alleged that claims 59 and 60 fail to limit further the subject matter of a previous claim. Claims 59 and 60 have been cancelled, thereby obviating the rejection with regard to those claims.

The Examiner has objected to claims 52-57. In particular, the Examiner has alleged that “and” should be placed between the last amino acid defined and the ‘Cys at ...’. Claims 52-57 have been so amended.

In view of the foregoing, Applicants respectfully request the withdrawal of the objections to claims 40, 47-57, and 59-60.

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Response to the Rejection under 35 U.S.C. §112, Second Paragraph

Claims 40 and 47-64 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Reconsideration is respectfully requested in view of the amendments and remarks herein.

With regard to claim 40, the Examiner has alleged that “[i]t is unclear whether applicant is claiming a collection, e.g., an array, of compounds and their salts, or whether Applicant intended to claim ‘A compound... or a pharmaceutically acceptable salt thereof.’” (Office Action, page 6). Additionally, claims 40, 48, and 49 have been objected to as reciting “or” between the last amino acid and the P2 and P2’. Moreover, the Examiner has raised various other objections to claim 40 as set forth in the Office Action. Claim 40 has been amended to replace “Compounds” with --A compound-- and to delete the “or” between the last amino acid and the P2 and P2’. Moreover, claim 40 has been further amended as presented herein. Additionally, claims 50 and 51 have been amended to recite --The compound-- instead of “Compounds.” Applicants respectfully submit that the amendments to claims 40, 50, and 51 obviate the basis for the rejection with regard to those claims.

Claims 47-49 have been cancelled, thereby obviating the rejection with regard to those claims.

Claims 52-57 have been rejected as allegedly lacking clear antecedent basis. In particular, the Examiner has alleged that “‘A compound of claim 1’ is unclear as to whether it refers back to formula (I) or portion of formula (I).” (Office Action, page 8). Moreover, the Examiner has indicated that the dependent claims, e.g., claim 52 should recite --The compound of-- rather than “A compound.” Claims 52-57 have been amended to recite --The compound of-- rather than “A compound.” Applicants respectfully submit that the amendments to claims 40 and 52-57 obviate the basis for the rejection with regard to claims 52-57.

Claim 58 has been rejected as allegedly lacking antecedent basis. In particular, the Examiner has alleged that "it is unclear as to what Applicant is intending as the enantiomer of the compound, in that claim 40 only allows for an optional D-isomer amino acid at one position." (Office Action, page 8). Applicants respectfully submit that the amendment to claim 40 to recite "an enantiomer thereof" obviates the rejection with regard to claim 58.

Moreover, Applicants wish to point out that an enantiomer is the exact mirror image of a chiral compound (i.e., a compound containing at least one asymmetric carbon atom). Each chiral building block of a chiral compound is replaced, in the enantiomer of such chiral compound, by its optical antipode. Thus, if a given chiral compound contains residues such as ^LAla, ^LPro, ^LGlu, ^DArg, etc., its enantiomer contains, at the respective positions, instead the residues ^DAla, ^DPro, ^DGlu, ^LArg, etc. However, where the chiral compound in question contains Gly at a certain position, its enantiomer contains, at the respective position, also Gly, seeing that Gly contains no center of asymmetry. To prepare an enantiomer, one has to replace all chiral starting materials with their enantiomers.

Claims 59-60 have been cancelled, thereby obviating the rejection with regard to those claims.

Moreover, Applicants respectfully submit that claim 61 as presented herein is definite.

Claims 62-64 have been rejected as drawn to "compositions." In particular, the Examiner has alleged that "it is unclear whether Applicant is claiming a set of compositions, or whether Applicant intended to claim 'A composition.'" (Office Action, page 8). Claims 62-64 have been amended herein to replace "Compositions" with --A composition--. Applicants respectfully submit that the amendments to claims 62-64 obviate the basis for the rejection with regard to those claims.

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In view of the foregoing, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §112, second paragraph, with regard to claims 40 and 47-64.

Response to the Rejection under 35 U.S.C. §112, first paragraph, Written Description

Claims 40, 47-49 and 58-64 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Reconsideration is respectfully requested in view of the amendments and remarks herein.

To advance prosecution, claim 40 has been amended herein. Applicants respectfully submit that the amendment to claim 40 obviates the rejection with regard to that claim.

Claims 47-49 and 59-60 have been cancelled herein. The cancellation of claims 47-49 and 59-60 obviates the rejection with regard to those claims.

Claims 58 and 61-64 all depend either directly or indirectly from claim 40. Applicants respectfully submit that the amendment to claim 40 obviates the rejection with regard to claims 58 and 61-64.

In view of the foregoing, withdrawal of the rejection of claims 40, 47-49, and 58-64 under 35 U.S.C. §112, first paragraph, for alleged lack of written description is respectfully requested.

Response to the Rejection under 35 U.S.C. §112, first paragraph, Enablement

Claims 40, 47-49 and 58-64 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Reconsideration is respectfully requested in view of the amendments and remarks herein.

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To advance prosecution, claim 40 has been amended herein. Applicants respectfully submit that the amendment to claim 40 obviates the rejection with regard to that claim.

Claims 47-49 and 59-60 have been cancelled herein. The cancellation of claims 47-49 and 59-60 obviates the rejection with regard to those claims.

Claims 58 and 61-64 all depend either directly or indirectly from claim 40. Applicants respectfully submit that the amendment to claim 40 obviates the rejection with regard to claims 58 and 61-64.

In view of the foregoing, withdrawal of the rejection of claims 40, 47-49, and 58-64 under 35 U.S.C. §112, first paragraph, for alleged lack of enablement is respectfully requested.

Concluding Remarks

An allowance of the claims is respectfully requested. Should the Examiner have any questions or comments concerning the foregoing, the Examiner is respectfully invited to contact the undersigned at the telephone number given below.

No fees are deemed due. However, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of

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time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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